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Food and Drug Administration
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RTF Infant Formulas: Problems & Solution

Dear Ms. DeRoeve,

As the general function of the Food Advisory Committee is to provide advice and recommendations to the agency, I would greatly appreciate it if you provide copies of this letter to the distinguished members of the Food Advisory Committee in the meeting on Infant Formula, April 4-5, 2002.

Background:

The top two recommendations of the American Academy of Pediatrics (AAP) pertinent to infant nutrition are:

- 1) *The AAP will continue to promote breastfeeding as the best form of infant nutrition.*
- 2) *The AAP will continue to work to maintain and improve the high quality of infant formulas in United States, because in some cases breastfeeding is not practical or desired.*

The Infant Formula Act of 1980 specifies that an infant formula must contain nutrients in accordance with the levels recommended by the AAP Committee on Nutrition. The Academy, through its Committee on Nutrition, will continue to maintain and improve the high quality of infant formulas in this country. Infant formulas must contain nutrients as listed in the U.S. Code of Federal Regulations 21 CFR 107.100 (Revised as of April 1, 2001 - Table 1). There are no set maximum levels for most of the vitamins and half of the minerals.

Ready-To-Feed (RTF) infant formulas in the market are available as sterilized (retorted or UHT-treated) products. These products are generally sold in hermetically sealed containers such as cans and are intended to have a shelf-life of up to 1½ years at room temperature.

Problems:

RTF infant formulas, like many liquid food products, go through physical, chemical, and enzymatic reactions during storage. The rate of such reactions follows the well-known Arrhenius equation ($k = k_0 e^{-E_a/RT}$). This means that the higher the storage temperature (e.g., room temperature vs. refrigerated temperature), the higher the rate of the reaction. The extent of such reactions, formation of by-products and loss of nutrients is a function of storage time. This means that the longer the storage time (e.g., 1½ years vs. few weeks), the more the extent of reaction.

Storage of RTF infant formulas at room temperature can result in a host of undesirable defects such as the destruction of vitamins, which are necessary to the integrity of the overall product. To account for such degradation during sterilization and especially long-term storage, manufacturers must over-load infant formula with vitamins to ensure the products will meet the label requirement of nutrients at the end of their shelf-life. The costly overloading solves the requirements of label claim but may present a health problem.

In fact since sterilized RTF products are designed to have a shelf-life of up to 1½ years at room temperature, such products will have a different actual content of degradable vitamins and nutrients in the early part of their shelf-life as compared to the latter part. Thus, an infant will obtain a different and unknown amount of vitamins depending on when the sterilized product stored at room temperature is consumed.

Another problem with UHT-treated infant formulas is that the bacterial enzymes survive this process to a high degree and result in such problems as off-flavor and gelation during storage at room temperature. To reduce the activity of the surviving enzymes, the products need to be stored at refrigerated temperature.

Long-term metabolic and health effects of over-loading of infant formulas are not known. Can feeding such over-loaded infant formulas (that must meet the label claim at the end 1½ years storage at room temperature) to infants have any role in the rise of over-weight and obese children in later years of life? Can feeding such products have any role in the rise of type II diabetes in children in later years of life? Unfortunately, over-weight, obesity and type II diabetes in children and younger adults are on rise and this problem needs attention of the responsible and regulatory agencies.

How can these opposite demands (i.e., not over-loading vs. meeting the label claim at the end of the product's shelf-life) be reconciled? I believe suggestions to arbitrarily set high maximum levels of vitamins in order to legally allow over-loading and, therefore, meeting the label claim at the end of 1½ years storage at room temperature, is a simplistic -if not irresponsible- solution. I am proposing a science-based practical solution in this regard and ask for your attention.

A Science-Based Practical Solution:

One solution to the above problem is to reduce the storage temperature (refrigerated temperature of 33-40 °F instead of room temperature) and storage time (up to 2 months instead of up to 1½ years) of RTF infant formulas. The refrigerated storage will preserve the overall quality and taste of product. This is because the rate and extent of physical, chemical, and enzymatic reactions (including vitamin degradation and off-flavor formation and gelation) are decreased at the lower temperatures and, therefore, there will not be a need for over-loading in the first place.

The most practical way is not to over-load RTF infant formulas but store them in the refrigerated dairy sections of supermarkets for up to two months. Alternatively, pasteurized or ultra-pasteurized RTF infant formulas (similar to pasteurized or ultra-pasteurized fresh milk) with no over-loading and no concern for long-term health effect should be considered. Prototypes of pasteurized or ultra-pasteurized RTF infant formulas have already been developed.

Should FDA and AAP determine that the un-necessary over-loading of RTF infant formulas (because of storage at room temperature for up to 1½ years) is not linked to any long-term health effects (such as over-weight, obesity and diabetes type II) in children and younger adults, the public will be well served if such conclusion is publicly announced by the responsible authorities.

Thank you for your cooperation and I wish the best of success for your meeting. If you have any comments or questions, please do not hesitate to contact me.

Sincerely,



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CC: Dr. Louis Cooper, President of American Academy of Pediatrics

TABLE 1

An infant formula shall contain the following nutrients at a level not less than the minimum level specified and not more than the maximum level specified for each 100 kilocalories of the infant formula in the form prepared for consumption as directed on the container
(21CFR107.100-2001)

Nutrients	Unit of measurement	Minimum level	Maximum level
Protein	Grams	1.8	4.5
Fat	do	3.3	6.0
	Percent calories	30	54
Linoleic acid	Milligrams	300
	Percent calories	2.7
Vitamins			
Vitamin A	International Units	250	750
Vitamin D	do	40	100
Vitamin E	do	0.7
Vitamin K	Micrograms	4
Thiamine (vitamin B1)	do	40
Riboflavin (vitamin B2)	do	60
Vitamin B6	do	35
Vitamin B12	do	0.15
Niacin ¹	do	250
Folic acid (folacin)	do	4
Pantothenic acid	do	300
Biotin ²	do	1.5
Vitamin C (ascorbic acid)	Milligrams	8
Choline ²	do	7
Inositol ²	do	4
Minerals			
Calcium	do	60
Phosphorus	do	30
Magnesium	do	6
Iron	do	0.15	3.0
Zinc	do	0.5
Manganese	Micrograms	5
Copper	Micrograms	60
Iodine	do	5	75
Sodium	Milligrams	20	60
Potassium	do	80	200
Chloride	do	55	150